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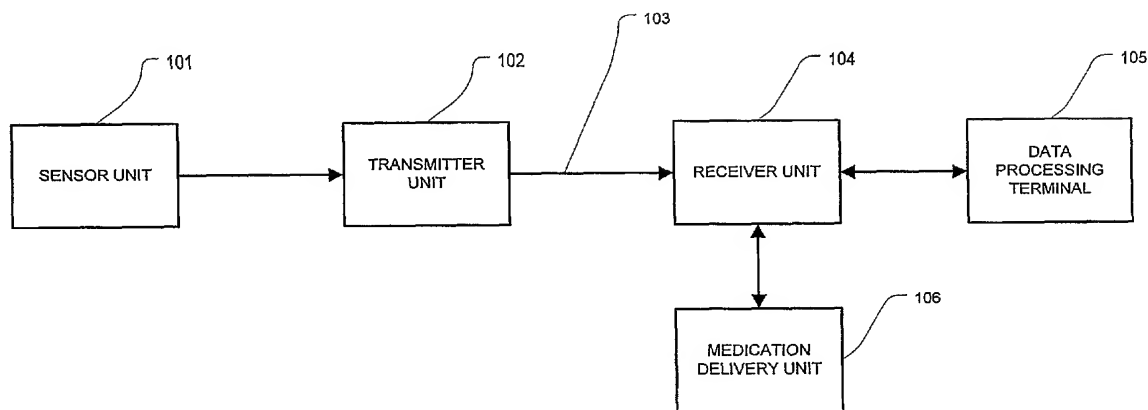
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(54) Title: METHOD AND SYSTEM FOR PROVIDING DATA COMMUNICATION IN CONTINUOUS GLUCOSE MONITOR-  
ING AND MANAGEMENT SYSTEM



(57) Abstract: Method and system for providing data monitoring and management including RF communication link over which a transmitter and a receiver is configured to communicate, the transmitter configured to periodically transmit a data packet associated with a detected analyte level received from an analyte sensor, and the receiver configured to identify the transmitter as the correct transmitter for which it is configured to receive the data packets, and to continue to receive the data packets from the transmitter once the transmitter identification has been verified, is provided.

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## METHOD AND SYSTEM FOR PROVIDING DATA COMMUNICATION IN CONTINUOUS GLUCOSE MONITORING AND MANAGEMENT SYSTEM

### RELATED APPLICATIONS

5           This application claims priority under 35 USC §119 to Provisional Patent  
Application No 60/545,362 filed on February 17, 2004, entitled "RF Link Protocol  
For Data Communication Systems", and under 35 USC §120 to pending Application  
No. 10/745,878 filed on December 26, 2003 entitled "Continuous Glucose  
Monitoring System and Methods of Use", the disclosure of each of which are  
10           incorporated herein by reference for all purposes.

### BACKGROUND

          The present invention relates to in-vivo continuous glucose monitoring and  
management system. More specifically, the present invention relates to  
15           communication protocol for data communication between, for example, a transmitter  
and a receiver, in the continuous glucose monitoring and management systems for  
insulin therapy.

          In data communication systems such as continuous glucose monitoring  
systems for insulin therapy, analyte levels such as glucose levels of a patient is  
20           continuously monitored and the measured glucose levels are used to diabetes  
treatment. For example, real time values of measured glucose levels would allow for  
a more robust and accurate diabetes treatment. Indeed, accurately measured glucose  
levels of a diabetic patient would enable a more effective insulin therapy by way of  
more timely bolus determination and administration.

25           In such data monitoring systems, it is important for the measured glucose  
levels or data to be effectively and be less error prone in data transmission and/or  
manipulation. Indeed, it would be desirable to have a continuous glucose monitoring  
and management system that provides a robust and substantially error free data  
communication between the components or electronic devices in the system. More  
30           specifically, it would be desirable to have a reliable communication protocol between  
the transmitter and the receiver in a continuous glucose monitoring and management  
system that allows for substantially real time data communication between the

transmitter and the receiver for communicating data signals associated with the components such as component identification information as well as measured glucose values.

#### SUMMARY OF THE INVENTION

In accordance with the various embodiments of the present invention, there is provided method and system for providing RF communication protocol between one or more signal transmission devices and one or more corresponding signal reception devices in a data monitoring and management system such as continuous glucose monitoring systems.

In one embodiment, there is provided an RF communication link, a transmitter coupled to the communication link where the transmitter periodically transmits a data packet at a given time interval over the communication link to a receiver that receives a first transmitted data packet, and once the transmitter identification has been verified, the receiver continues receiving subsequent data packets from the transmitter.

In one embodiment, the receiver may be configured to verify the transmitter identification based on the transmitter identification information encoded with the first transmitted data packet.

In a further embodiment, a medication delivery unit such as an insulin pump may be provided and that is configured to communicate with the receiver to receive detected glucose level of a patient. In such a case, the transmitter may be configured to be in signal communication with an analyte sensor such as a blood glucose sensor that repeatedly measures blood glucose level of a patient at a predetermined time interval and transmits that information to the transmitter subsequent transmission, over the RF communication link, to the receiver. The receiver/monitor may be configured to display the measured glucose level information including, for example, trend information, as well as to perform other functions such as bolus and/or basal rate modification determinations.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a continuous glucose monitoring and management system in accordance with one embodiment of the present invention;

FIG. 2 is a block diagram of the transmitter of the system shown in FIG. 1 in accordance with one embodiment of the present invention;

FIG. 3 is a block diagram of the receiver of the system shown in FIG. 1 in accordance with one embodiment of the present invention;

FIG. 4 is an illustration of the application data including the sensor data from the transmitter of the system shown in FIG. 1 in accordance with one embodiment of the present invention;

FIGS. 5A-5C illustrate a data packet table for Reed-Solomon encoding in the transmitter, a depadded data table, and a data packet transmitted from the transmitter, respectively, in accordance with one embodiment of the system of FIG. 1;

FIG. 6 illustrates the data packet transmit window and time slots for transmission from the transmitter in one embodiment of the present invention;

FIG. 7 illustrates the timing of the transmitted data packet transmission by the transmitter and reception by the receiver in one embodiment of the present invention;

FIG 8 illustrate data packet at the receiver for demodulation in accordance with one embodiment of the present invention; and

FIG. 9 is a flowchart illustrating the transmitter – receiver communication of the system shown in FIG. 1 in accordance with one embodiment of the present invention.

### DETAILED DESCRIPTION

FIG. 1 illustrates a continuous glucose monitoring and management system 100 in accordance with one embodiment of the present invention. In such embodiment, the continuous glucose monitoring and management system 100 includes a sensor 101, a transmitter 102 coupled to the sensor 101, and a receiver 104 which is configured to communicate with the transmitter 102 via a communication link 103. The receiver 104 may be further configured to transmit data to a data processing terminal 105 for evaluating the data received by the receiver 104.

Referring again to the Figure, also shown in FIG.1 is a medication delivery unit 106 which is operatively coupled to the receiver 104. In one embodiment, the medication delivery unit 106 may be configured to administer a predetermined or calculated insulin dosage based on the information received from the receiver 104. For  
5 example, as discussed in further detail below, the medication delivery unit 106 in one embodiment may include an infusion pump configured to administer basal profiles to diabetic patients, as well as to determine and/or administer one or more suitable boluses for the diabetic patients.

Only one sensor 101, transmitter 102, communication link 103, receiver 104,  
10 and data processing terminal 105 are shown in the embodiment of the continuous glucose monitoring and management system 100 illustrated in FIG. 1. However, it will be appreciated by one of ordinary skill in the art that the continuous glucose monitoring and management system 100 may include one or more sensor 101,  
transmitter 102, communication link 103, receiver 104, and data processing terminal  
15 105, where each receiver 104 is uniquely synchronized with a respective transmitter 102.

In one embodiment of the present invention, the sensor 101 is physically positioned on the body of a user whose glucose level is being monitored. The term user as used herein is intended to include humans, animals, as well as any other who  
20 might benefit from the use of the glucose monitoring and management system 100. The sensor 101 maybe configured to continuously sample the glucose level of the user and convert the sampled glucose level into a corresponding data signal for transmission by the transmitter 102. In one embodiment, the transmitter 102 is mounted on the sensor 101 so that both devices are positioned on the user's body.  
25 The transmitter 102 performs data processing such as filtering and encoding on data signals, each of which corresponds to a sampled glucose level of the user, for transmission to the receiver 104 via the communication link 103.

In one embodiment, the continuous glucose monitoring and management system 100 is configured as a one-way RF communication path from the transmitter  
30 102 to the receiver 104. In such embodiment, the transmitter 102 is configured to continuously and repeatedly transmit the sampled data signals received from the

sensor 101 to the receiver 104, without acknowledgement from the receiver 104 that the transmitted sampled data signals have been received. For example, the transmitter 102 may be configured to transmit the encoded sampled data signals at a fixed rate (e.g., at one minute intervals) after the completion of the initial power on procedure. Likewise, the receiver 104 may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. While a uni-directional communication path from the transmitter 102 to the receiver 104 is described herein, within the scope of the present invention, a bi-directional communication between the transmitter 102 and the receiver 104 is also included. Indeed, the transmitter 102 may include a transceiver to enable both data transmission and reception to and from the receiver 104 and/or any other devices communicating over the communication link 103 in the continuous data monitoring and management system 100.

As discussed in further detail below, in one embodiment of the present invention the receiver 104 includes two sections. The first section is an analog interface section that is configured to communicate with the transmitter 102 via the communication link 103. In one embodiment, the analog interface section may include an RF receiver and an antenna for receiving and amplifying the data signals from the transmitter 102, which are thereafter demodulated with a local oscillator and filtered through a band-pass filter. The second section of the receiver 104 is a data processing section which is configured to process the data signals received from the transmitter 102 such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery.

In operation, upon completing the power-on procedure, the receiver 104 is configured to detect the presence of the transmitter 102 within its range based on the strength of the detected data signals received from the transmitter 102. For example, in one embodiment, the receiver 104 is configured to detect signals whose strength exceeds a predetermined level to identify the transmitter 102 from which the receiver 104 is to receive data. Alternatively, the receiver 104 in a further embodiment may be configured to respond to signal transmission for a predetermined transmitter identification information of a particular transmitter 102 such that, rather than detecting the signal strength of a transmitter 102 to identify the transmitter, the

receiver 104 may be configured to detect transmitted signal from a predetermined transmitter 102 based on the transmitted transmitter identification information corresponding to the pre-assigned transmitter identification information for the particular receiver 104.

5 In one embodiment, the identification information of the transmitters 102 includes a 16-bit ID number. In an alternate embodiment, the ID number may be a predetermined length including a 24-bit ID number or a 32-bit ID number. Further, any other length ID number may also be used. Thus, in the presence of multiple transmitters 102, the receiver 104 will only recognize the transmitter 102 which  
10 corresponds to the stored or reconstructed transmitter identification information. Data signals transmitted from the other transmitters within the range of the receiver 104 are considered invalid signals.

Referring again to FIG. 1, where the receiver 104 determines the corresponding transmitter 102 based on the signal strength of the transmitter 102,  
15 when the receiver 104 is initially powered-on, the receiver 104 is configured to continuously sample the signal strength of the data signals received from the transmitters within its range. If the signal strength of the data signals meets or exceeds the signal strength threshold level and the transmission duration threshold level, the receiver 104 returns a positive indication for the transmitter 102  
20 transmitting the data signals. That is, in one embodiment, the receiver 104 is configured to positively identify the transmitter 102 after one data signal transmission. Thereafter, the receiver 104 is configured to detect positive indications for two consecutive data signals transmissions for a predetermined time period. At such point, after three consecutive transmissions, the transmitter 102 is fully  
25 synchronized with the receiver 104.

Upon identifying the appropriate transmitter 102, the receiver 104 begins a decoding procedure to decode the received data signals. In one embodiment, a sampling clock signal may be obtained from the preamble portion of the received data signals. The decoded data signals, which include fixed length data fields, are then  
30 sampled with the sampling clock signal. In one embodiment of the present invention, based on the received data signals and the time interval between each of the three data

signal transmissions, the receiver 104 determines the wait time period for receiving the next transmission from the identified and synchronized transmitter 102. Upon successful synchronization, the receiver 104 begins receiving from the transmitter 102 data signals corresponding to the user's detected glucose level. As described in further detail below, the receiver 104 in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter 102 via the communication link 103 to obtain the user's detected glucose level.

Referring yet again to FIG. 1, the data processing terminal 105 may include a personal computer, a portable computer such as a laptop or a handheld device (e.g., personal digital assistants (PDAs)), and the like, each of which is configured for data communication with the receiver via a wired or a wireless connection. Additionally, the data processing terminal 105 may further be connected to a data network (not shown) for storing, retrieving and updating data corresponding to the detected glucose level of the user.

FIG. 2 is a block diagram of the transmitter 102 of the continuous glucose monitoring and management system 100 in accordance with one embodiment of the present invention. The transmitter 102 includes an analog interface 201 configured to communicate with the sensor 101 (FIG. 1), a user input 202, and a temperature detection section 203, each of which is operatively coupled to a transmitter processing unit 204 such as a central processing unit (CPU). Further shown in FIG. 2 are a transmitter serial communication section 205 and an RF transmitter 206, each of which is also operatively coupled to the transmitter processing unit 204. Moreover, a power supply 207 is also provided in the transmitter 102 to provide the necessary power for the transmitter 102. Additionally, as can be seen from the Figure, clock 208 is provided to, among others, supply real time information to the transmitter processing unit 204.

In one embodiment, a unidirectional input path is established from the sensor 101 (FIG. 1) and/or manufacturing and testing equipment to the analog interface 201, while a unidirectional output is established from the output of the RF transmitter 206. In this manner, a data path is shown in FIG. 2 between the aforementioned unidirectional input and output via a dedicated link 209 from the analog interface 201



to serial communication section 205, thereafter to the processing unit 204, and then to the RF transmitter 206. As such, in one embodiment, through the data path described above, the transmitter 102 is configured to transmit to the receiver 104 (FIG. 1), via the communication link 103 (FIG. 1), processed and encoded data signals received from the sensor 101 (FIG. 1). Additionally, the unidirectional communication data path between the analog interface 201 and the RF transmitter 206 discussed above allows for the configuration of the transmitter 102 for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

Referring back to FIG. 2, the user input 202 includes a disable device that allows the operation of the transmitter 102 to be temporarily disabled, such as, by the user wearing the transmitter 102. In an alternate embodiment, the disable device of the user input 202 may be configured to initiate the power-up procedure of the transmitter 102.

As discussed above, the transmitter processing unit 204 is configured to transmit control signals to the various sections of the transmitter 102 during the operation of the transmitter 102. In one embodiment, the transmitter processing unit 204 also includes a memory (not shown) for storing data such as the identification information for the transmitter 102, as well as the data signals received from the sensor 101. The stored information may be retrieved and processed for transmission to the receiver 104 under the control of the transmitter processing unit 204.

Furthermore, the power supply 207 may include a commercially available battery pack.

The physical configuration of the transmitter 102 is designed to be substantially water resistant, so that it may be immersed in non-saline water for a brief period of time without degradation in performance. Furthermore, in one embodiment, the transmitter 102 is designed so that it is substantially compact and light-weight, not weighing more than a predetermined weight such as, for example, approximately 18 grams. Furthermore, the dimensions of the transmitter 102 in one embodiment includes 52 mm in length, 30 mm in width and 12 mm in thickness. Such small size and weight enable the user to easily carry the transmitter 102.

The transmitter 102 is also configured such that the power supply section 207 is capable of providing power to the transmitter for a minimum of three months of continuous operation after having been stored for 18 months in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processing unit 204 operating in low power modes in the non-operating state, for example, drawing no more than approximately 1  $\mu$ A. Indeed, in one embodiment, the final step during the manufacturing process of the transmitter 102 places the transmitter 102 in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter 102 may be significantly improved.

Referring again to FIG. 2, the analog interface 201 of the transmitter 102 in one embodiment includes a sensor interface (not shown) configured to physically couple to the various sensor electrodes (such as, for example, working electrode, reference electrode, counter electrode, (not shown)) of the sensor 101 (FIG.1) of the monitoring system 100. The analog interface section 201 further includes a potentiostat circuit (not shown) which is configured to generate the Poise voltage determined from the current signals received from the sensor electrodes. In particular, the Poise voltage is determined by setting the voltage difference between the working electrode and the reference electrode (i.e., the offset voltage between the working electrode and the reference electrode of the sensor 102). Further, the potentiostat circuit also includes a transimpedance amplifier for converting the current signal on the working electrode into a corresponding voltage signal proportional to the current. The signal from the potentiostat circuit is then low pass filtered with a predetermined cut-off frequency to provide anti-aliasing, and thereafter, passed through a gain stage to provide sufficient gain to allow accurate signal resolution detected from the sensor 101 for analog-to-digital conversion and encoding for transmission to the receiver 104.

Referring yet again to FIG. 2, the temperature detection section 203 of the transmitter 102 is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the glucose readings obtained from the analog interface 201. As discussed above, the input section 202 of the

transmitter 102 includes the disable device which allows the user to temporarily disable the transmitter 102 such as for, example, to comply with the FAA regulations when aboard an aircraft. Moreover, in a further embodiment, the disable device may be further configured to interrupt the transmitter processing unit 204 of the transmitter 102 while in the low power, non-operating mode to initiate operation thereof.

The RF transmitter 206 of the transmitter 102 may be configured for operation in the frequency band of 315 MHz to 322 MHz, for example, in the United States. Further, in one embodiment, the RF transmitter 206 is configured to modulate the carrier frequency by performing Frequency Shift Keying and Manchester encoding. In one embodiment, the data transmission rate is 19,200 symbols per second, with a minimum transmission range for communication with the receiver 104.

FIG. 3 is a block diagram of the receiver 104 of the continuous glucose monitoring and management system 100 in accordance with one embodiment of the present invention. Referring to FIG. 3, the receiver 104 includes a blood glucose test strip interface 301, an RF receiver 302, an input 303, a temperature detection section 304, and a clock 305, each of which is operatively coupled to a receiver processing unit 307. As can be further seen from the Figure, the receiver 104 also includes a power supply 306 operatively coupled to a power conversion and monitoring section 308. Further, the power conversion and monitoring section 308 is also coupled to the receiver processing unit 307. Moreover, also shown are a receiver communication section 309, and an output 310, each operatively coupled to the receiver processing unit 307.

In one embodiment, the test strip interface 301 includes a glucose level testing portion to receive a manual insertion of a glucose testing strip, and thereby determine and display the glucose level of the testing strip on the output 310 of the receiver 104. This manual testing of glucose can be used to calibrate sensor 101. The RF receiver 302 is configured to communicate, via the communication link 103 (FIG. 1) with the RF transmitter 206 of the transmitter 102, to receive encoded data signals from the transmitter 102 for, among others, signal mixing, demodulation, and other data processing. The input 303 of the receiver 104 is configured to allow the user to enter information into the receiver 104 as needed. In one aspect, the input 303 may include

one or more keys of a keypad, a touch-sensitive screen, or a voice-activated input command unit. The temperature detection section 304 is configured to provide temperature information of the receiver 104 to the receiver processing unit 307, while the clock 305 provides, among others, real time information to the receiver processing unit 307.

Each of the various components of the receiver 104 shown in FIG. 3 are powered by the power supply 306 which, in one embodiment, includes a battery. Furthermore, the power conversion and monitoring section 308 is configured to monitor the power usage by the various components in the receiver 104 for effective power management and to alert the user, for example, in the event of power usage which renders the receiver 104 in sub-optimal operating conditions. An example of such sub-optimal operating condition may include, for example, operating the vibration output mode (as discussed below) for a period of time thus substantially draining the power supply 306 while the processing unit 307 (thus, the receiver 104) is turned on. Moreover, the power conversion and monitoring section 308 may additionally be configured to include a reverse polarity protection circuit such as a field effect transistor (FET) configured as a battery activated switch.

The communication section 309 in the receiver 104 is configured to provide a bi-directional communication path from the testing and/or manufacturing equipment for, among others, initialization, testing, and configuration of the receiver 104. Serial communication section 104 can also be used to upload data to a computer, such as time-stamped blood glucose data. The communication link with an external device (not shown) can be made, for example, by cable, infrared (IR) or RF link. The output 310 of the receiver 104 is configured to provide, among others, a graphical user interface (GUI) such as a liquid crystal display (LCD) for displaying information. Additionally, the output 310 may also include an integrated speaker for outputting audible signals as well as to provide vibration output as commonly found in handheld electronic devices, such as mobile telephones presently available. In a further embodiment, the receiver 104 also includes an electroluminescent lamp configured to provide backlighting to the output 310 for output visual display in dark ambient surroundings.

Referring back to FIG. 3, the receiver 104 in one embodiment may also include a storage section such as a programmable, non-volatile memory device as part of the processing unit 307, or provided separately in the receiver 104, operatively coupled to the processing unit 307. The processor 307 is further configured to perform Manchester decoding as well as error detection and correction upon the encoded data signals received from the transmitter 102 via the communication link 103.

FIG. 4 is an illustration of the application data including the sensor data from the transmitter of the system shown in FIG. 1 in accordance with one embodiment of the present invention. Referring to FIG. 4, in one embodiment, each data packet from the transmitter 102 includes 15 bytes as shown in the Figure. For example, the first byte (zero byte) corresponds to the transmitter 102 transmit time information ("TxTime") which is a protocol value and is configured to start at zero and incremented with every data packet. In one embodiment, the transmit time (TxTime) data is used for synchronizing the transmit window hopping and error correction as discussed in further detail below. Referring back to FIG. 4, the transmit data packet also includes bytes 1 to 14 which comprise the application payload that includes signal representation of the glucose values measured by the sensor 101, and which is to be encoded with transmission protocol information and transmitted to the receiver 104. For example, in one embodiment, the transmission data packet is Reed Solomon encoded and transmitted to the receiver 104, which is configured to detect and correct up to 3 symbol errors. It should be noted that the Reed Solomon encoding discussed herein may be configured to perform forward error correction encoding on the transmission data packet prior to transmission to the receiver 104.

FIGS. 5A-5C illustrate a data packet table for Reed-Solomon encoding in the transmitter, a depadded data table, and a data packet transmitted from the transmitter, respectively, of the continuous glucose monitoring and management system of FIG. 1 in accordance with one embodiment. Referring to FIG. 5A, it can be seen that the Reed Solomon encoded data block contents include 15 bytes of packed data (FIG. 4), one byte of the least significant bit (LSB) of the transmitter identification information (TxID), one byte of the least middle significant bit of the transmitter identification

information (TxID), one byte of the most middle significant bit of the transmitter identification information (Tx ID), one byte of the most significant bit (MSB) of the transmitter identification information (TxID), 230 bytes of zero pads, 6 bytes of parity symbols, to comprise a total of 255 bytes.

5 In one embodiment, the Reed Solomon encode procedure at the transmitter 102 uses 8 bit symbols for a 255 symbol block to generate the 6 parity symbols. The encoding procedure may include the encoding of the transmitter identification information into the parity symbols. The transmitter 102 in one embodiment is configured to build the data portion (15 bytes of packed data) of the data block shown  
10 in FIG. 5A (for example, using a virtual realization of the table). The transmitter 102 is configured to remove the 230 bytes of zero pads, and the 4 bytes of transmitter identification information (TxID), resulting in the 21 bytes of depadded data block including the 15 bytes of packed data and the 6 bytes of parity symbols as shown in FIG. 5B.

15 In one embodiment, the transmitter identification information (Tx ID) is not included in the transmitted data transmitted from the transmitter 102 to the receiver 104. Rather, the receiver 104 may be configured to determine the transmitter identification information (Tx ID) from the received data by using Reed Solomon decoding. More specifically, when decoding the first data packet received from a  
20 transmitter 102, the receiver 104 may be configured to set the value corresponding to the transmitter identification information (TxID) to zero, and to indicate to the Reed Solomon decoder that the transmitter identification information (TxID) is known to be incorrect. The Reed Solomon decoder may then be configured to use this information to more effectively “correct” during the error correction procedure, and  
25 therefore to recover the transmitter identification information (TxID) from the received data. Indeed, in subsequent data packets, the received pads and the received data packet with the known transmitter identification information (TxID) are used to facilitate with the error detection.

30 Referring back to FIG C, a link prefix is added to the depadded data block to complete the data packet for transmission to the receiver 104. The link prefix allows the receiver 104 to align the byte boundaries associated the transmitted data from the

transmitter 102 for Reed Solomon decoding as described in further detail below. More specifically, as shown in FIG. 5C, the transmitter 102 is configured to add 4 bytes of link prefix (0x00, 0x00, 0x15, and 0x67) to the 21 bytes of depadded data block to result in 25 bytes of data packet. In this manner, once powered up and  
5 enabled in operational mode, the transmitter 102 is configured to transmit the 25 byte data packet once every minute. More specifically, in one embodiment, the transmitter 102 may be configured to Manchester encode the data at 2 Manchester bits per data bit (0 = 10; 1 = 01), and transmit the Manchester bits at 20,000 Manchester bits per second. It should be noted here that the Manchester encoding in one embodiment is  
10 configured to encode the data clock with the transmitted data. Further, it may be configured to shift the frequency content up so that there is no DC (direct current) content. The transmitter 102 may be configured to transmit the data packets with the most significant bit - byte zero first.

In this manner, in one embodiment of the present invention, the transmitter  
15 102 may be configured to transmit a data packet once per minute, where the time between each data packet transmit may range between 50 to 70 seconds. In one embodiment, the transmitter may be configured to maintain a minute tick reference to schedule transmit windows as discussed in further detail below. The first data packet then may be scheduled relative to that time.

More specifically, the time that the data packet is transmitted by the  
20 transmitter 102 may vary from minute to minute. For example, in one embodiment, the first 10 seconds after a minute tick are divided into time windows each being 25 milliseconds wide, and numbered from 0 to 399. The transmitter 102 may then be configured to select the transmit window based upon a predetermined transmit  
25 configuration.

In one embodiment, the transmitter 102 may be configured to select to  
transmit window based on the transmitter identification information (TxID) and the transmit time information (TxTime). As discussed in further detail below, the  
transmit time (TxTime) represents a value that starts at zero and increments to 256  
30 for each data packet sent. When the transmit time (TxTime) is equal to zero, a pseudo random number generator is seeded with the transmitter identification

information (TxID). Then, for each minute, the pseudo random number generator may be used to generate the transmit window for that minute.

FIG. 6 illustrates the data packet transmit window and time slots for transmission from the transmitter in one embodiment of the present invention. In particular, the transmit window in one embodiment of the present invention may be configured such that 30 collocated transmitters may operate without any one of them losing data due to transmitter collisions. As discussed in further detail below, to prevent two or more transmitters from continuously colliding, a time hopping mechanism may be implemented to randomize the transmit time.

For example, each minute may be divided into 25 millisecond windows as shown in FIG. 6A. As shown in the Figure, a one second window may be divided into 40 time slots, and further, a one minute window may be segmented into 2,400 time slots for transmission. With the transmitter configured to transmit on average once per minute, the data burst is 200 bits long including preamble and a 1 millisecond transmitter warm up, resulting in approximately 25 millisecond burst duration.

Accordingly, in order to prevent transmission from two transmitters from continuously colliding with each other, the transmit time may be offset on each transmission as shown in FIG. 6B. In one embodiment, the transmit time offset configuration may be implemented as a function of the transmission identification information (TxID) and the transmit time (TxTime).

For example, in one embodiment, with the transmission at once per minute plus 10 seconds, during this 10 second period, 80 time segment windows may be reserved from sensor measurements. Thus since there are 40 transmission windows per each second, the 10 second duration results in 400 transmission windows from which the 80 time segment windows is deducted (for sensor measurement). This results in 320 possible transmission windows to select when to transmit the data packet by the transmitter 102. In one embodiment, the transmit time (TxTime) may be 8 bits, and each transmitter may be configured to select a time slot from the 320 possible transmission windows for data transmission. It should also be noted here that once the receiver 104 corresponding to a particular transmitter 102 is aware of



the transmit time (TxTime) associated with the transmitter 102, the receiver 104 may determine the future transmit window times associated with the transmitter 102 without additional information from the transmitter 102. This provides substantial advantages, for example, from power savings perspective, in that the receiver 104 may substantially accurately anticipate the transmit window for data transmission from the transmitter 102, and thus capture and receive substantially all of the transmitted data packets from the transmitter 102 without continuously listening out for the transmission data.

FIG. 7 illustrates the timing of the transmitted data packet transmission by the transmitter and reception by the receiver in one embodiment of the present invention. Referring to the Figure, in one embodiment, the receive window for the receiver 104 may be configured to be synchronized with the corresponding transmitter when a start indicator of the transmission is detected by the receiver 104. For example, the receiver 104 may be configured to synchronize the receive window with the associated transmitter 102 accurately with a phase locked start indicator. From the phase locked start indicator, the receiver 104 may predict the subsequent transmit burst time, with the error being limited to the relative drift between transmissions. When a transmit data packet is missed, the receiver 104 may be configured to widen the receive window. In one embodiment, the receive window may be configured relatively narrow so as to maintain the duty cycle low. In the case where the transmitter time drifts substantially to cause the receiver to miss a transmission, the next receive window may be configured to open substantially relatively wide to ensure that the data packet is not missed.

Referring back to the Figures, and each transmission time, the transmitter 02 is configured to send a data packet which is Manchester encoded, at two Manchester bits per data bit, with 1,900 Manchester bits per second. More specifically, the transmit data packet received by the receiver 104 in one embodiment comprises a dotting pattern, a data start indicator, and a forward error correction data as shown in FIG. 7. In one embodiment, the receiver 104 may be configured to use the dotting pattern to phase lock to the received signal and to extract the transmitted data clock information.

For optimal accuracy, in one embodiment, the received data should be sampled in the middle of the bit time. The receiver 104 needs to maintain phase lock to the data to limit the accumulation of timing error. Referring again to FIG. 7, the start indicator is configured to provide immunity to bit errors during data  
5 synchronization. More specifically, after determining the bit time and phase, the receiver 104 is configured to start collecting and saving the received data bits. The receiver 104 may be configured to search the received bit stream for data start indicator. In one embodiment, a 12-bit start indicator may be immune to all 2 bit errors. In other words, the receiver 104 may be configured such that it does not false  
10 detect or miss the start indicator with up to 2 bit errors. In one embodiment, a 13 bit start indicator may be used.

Referring again to FIG. 7, the transmitter identification information (TxID) may in one embodiment be used to schedule transmit time. As discussed above, the transmitter identification information (TxID) may be included in the forward error  
15 correction parity determination, and not transmitted with the transmission data packet.

Furthermore, the receiver 104 may be configured to discard a data packet when one of the following error conditions are detected. First, the receiver 104 may be configured to discard the data packet where the Reed Solomon decoding procedure indicates that the data packet is uncorrectable. Second, after decoding, the receiver  
20 104 may be configured to verify that all of the zero pad symbols are zero. A non-zero indicates that the Reed Solomon decode procedure has inadvertently “corrected” a pad byte from zero to some other value. In this case, the receiver 104 is configured to discard the associated data packet.

Third, after decoding, the receiver 104 is configured to verify that the  
25 transmitter identification information (TxID) pad symbols correspond to the correct the transmitter identification information (TxID). Again, an incorrect value representing the transmitter identification information (TxID) indicates that the Reed Solomon decode procedure has inadvertently “corrected” a pad byte to some other value. In this case, as before, the receiver 104 is configured to discard the data packet  
30 associated with the incorrect transmitter identification information (TxID). Finally, an unexpected value associated with the transmit time (TxTime) for the data packet

will indicate an error, since the transmit time (TxTime) is a predictable and determinable value, and which increments for every packet transmitted, as discussed above. In this case, the receiver 104 is configured to discard the data packet associated with the unexpected transmit time (TxTime) value.

5 Furthermore, in certain cases, the receiver 104 may be prevented from receiving the correct data from an in range transmitter 102. These include missed data synchronization, uncorrectable data packet due to random noise, and uncorrectable data packet due to burst noise. On average, at worst received signal strength, the receiver 104 may miss one data packet every 1.7 days. Burst noise is a  
10 function of the physical location, including the colliding of two transmitters that have overlapping transmission range. As discussed herein, the time hopping procedure makes it less likely that two transmitters will collide several times consecutively.

FIG 8 illustrate data packet at the receiver for demodulation in accordance with one embodiment of the present invention. As discussed above, the receiver 104  
15 in one embodiment may be configured to demodulate or extract the data clock from the received signal and to capture the received bit stream. More specifically, during the receiver 104 bit synchronization, the receiver 104 may be configured to establish phase lock during the leading zeros of the link prefix, to maintain the phase lock during the entire received bit stream, to save the data packet contents with the most  
20 significant bit first, or to save the data packet contents byte zero first.

With respect to receiver 104 frame synchronization, the receiver 104 in one embodiment may be configured to identify a bit sequence that is a Hamming distance of 2 or less from the transmitted data start indicator (FIG. 7). Moreover, the receiver 104 may be configured so that the received bit stream is byte aligned using the first  
25 data bit as the first byte boundary.

In one embodiment, the receiver 104 may be configured to wait up to 70 seconds for a data packet. The receiver 104 may be configured to perform synchronized time hopping with a corresponding transmitter 102, and to maintain time hop synchronization for more than 30 minutes, for example, of un-received data  
30 packets. Alternatively, the receiver in one embodiment may be configured to maintain time hop synchronization with the relative temperature changes of the

transmitter and receiver from the minimum and maximum crystal frequency extremes, which tests the ability of the receiver 104 to track the transmitter 102 time base as the crystal frequency of both devices changes with temperature.

Referring back to the Figures, the receiver 104 is configured to perform Reed Solomon decode procedure to the received data packet received from the transmitter 102. More specifically, the receiver 104 in one embodiment is configured to build the Reed Solomon data block contents as shown in FIG. 4 from the data packet received from the transmitter 102. Again, the packed data are the first 15 bytes of the received packet, and the parity symbols are the next 6 bytes. The zero pad bytes are set to zero.

Additionally, the receiver 104 may be configured to perform error detection and corrections including determining whether the Reed Solomon decode function returns a success, whether all of the 230 zero pad bytes are still zero, where in each of the case, the receiver 104 is configured to discard the data packet if any of these checks fail. More over, in the case where the receiver 104 has acquired a corresponding transmitter 102, the receiver 104 may be configured to check that the 32 bit transmitter identification information (TxID) is correct, and also, whether the transmit window time (TxTime) value is accurate (i.e., incrementing every minute). If any of these checks fail, the receiver 104 flags an error, and is configured to discard the data packet associated with the error.

FIG. 9 is a flowchart illustrating the transmitter – receiver communication of the system shown in FIG. 1 in accordance with one embodiment of the present invention. Referring to FIG. 9, upon completing the power up procedure as discussed above, the receiver 104 listens for the presence of a transmitter within the RF communication link range. When the transmitter 102 is detected within the RF communication link range at step 901, in one embodiment, the receiver 104 may be configured to receive and store the identification information corresponding to the detected transmitter 102. Alternatively, the receiver 102 may be pre-configured with the corresponding transmitter identification information, and thus, will be configured to verify the transmitter identification based on the data transmission received detected at step 901. More specifically, at step 901, the receiver 104 may be

configured to detect (or sample) data transmission within its RF communication range. In one aspect, the receiver 104 may be configured to identify a positive data transmission upon ascertaining that the data transmission is above a predetermined strength level for a given period of time (for example, receiving three separate data signals above the predetermined strength level from the transmitter 102 at one minute intervals over a period of five minutes).

At step 902, the receiver 104 is configured to determine whether the detected signals within the RF communication range is transmitted from the transmitter 102 having the transmitter identification information stored or reconstructed (e.g., regenerated) in the receiver 104. If it is determined at step 902 that the detected data transmission at step 901 does not originate from the transmitter corresponding to the transmitter identification information, then the procedure returns to step 901 and awaits for the detection of the next data transmission.

On the other hand, if at step 902 it is determined that the detected data transmission is from the transmitter 102 corresponding to the transmitter identification information, then at step 903, the receiver proceeds with decoding the received data and performing error correction thereon. In one embodiment, the receiver is configured to perform Reed-Solomon decoding, where the transmitted data received by the receiver is encoded with Reed-Solomon encoding. Furthermore, the receiver is configured to perform forward error correction to minimize data error due to, for example, external noise, and transmission noise.

Referring back to FIG. 9, after decoding and error correcting the received data, the receiver 104 at step 904 generates output data corresponding to the decoded error corrected data received from the transmitter 102, and thereafter, at step 905, the receiver 104 outputs the generated output data for the user as a real time display of the output data, or alternatively, in response to the user operation requesting the display of the output data. Additionally, before displaying the output data for the user, other pre-processing procedures may be performed on the output data to for example, smooth out the output signals. In one aspect, the generated output data may include a visual graphical output displayed on the graphical user interface of the

receiver. Alternatively, the output data may be numerically displayed representing the corresponding glucose level.

Referring to FIGS. 1 and 9, in one aspect of the present invention, the generated data output at step 906 may be provided to the medication delivery unit 106 (FIG. 1) to for analysis and therapy management, such as bolus calculations and basal profile modifications to alter or otherwise adjust the level of insulin dosage administered to the patient via the medication delivery unit 106 which may include an insulin pump.

Referring again to the Figures discussed above, the time hopping procedure of one embodiment is described. More specifically, since more than one transmitter 102 may be within the receiving range of a particular receiver 104, and each transmitting data every minute on the same frequency, transmitter units 102 are configured to transmit data packets at different times to avoid co-location collisions (that is, where one or more receivers 104 cannot discern the data signals transmitted by their respective associated transmitter units 102 because they are transmitting at the same time.)

In one aspect, transmitter 102 is configured to transmit once every minute randomly in a window of time of plus or minus 5 seconds (i.e., it time hops.) To conserve power, receiver 104 does not listen for its associated transmitter 102 during the entire 10 second receive window, but only at the predetermined time it knows the data packet will be coming from the corresponding transmitter 102. In one embodiment, the 10 second window is divided into 400 different time segments of 25 milliseconds each. With 80 time segments reserved for sensor measurements as discussed above, there remaining 320 time segments for the transmission. Before each RF transmission from the transmitter 102 takes place, both the transmitter 102 and the receiver 104 is configured to recognize in which one of the 320 time segments the data transmission will occur (or in which to start, if the transmission time exceeds 25 milliseconds.) Accordingly, receiver 104 only listens for a RF transmission in a single 25 millisecond time segment each minute, which varies from minute to minute within the 10 second time window.

Moreover, each transmitter 102 is configured to maintain a “master time” clock that the associated receiver unit 104 may reference to each minute (based on the time of transmission and known offset for that minute.). A counter also on the transmitter 102 may be configured to keep track of a value for transmit time (TxTime) that increments by 1 each minute, from 0 to 255 and then repeats. This transmit time (TxTime) value is transmitted in the data packet each minute, shown as Byte 0 in FIG. 4. Using the transmit time (TxTime) value and the transmitter’s unique identification information, both the transmitter 102 and the receiver 104 may be configured to calculate which of the 320 time segments will be used for the subsequent transmission. In one embodiment, the function that is used to calculate the offset from the master clock 1-minute tick is a pseudo-random number generator that uses both the transmit window (TxTime) and the transmitter identification information (TxID) as seed numbers. Accordingly, the transmission time varies pseudo-randomly within the 10 second window for 256 minutes, and then repeats the same time hopping sequence again for that particular transmitter 102.

In the manner described above, in accordance with one embodiment of the present invention, co-location collisions may be avoided with the above-described time hopping procedure. That is, in the event that two transmitters interfere with one another during a particular transmission, they are not likely to fall within the same time segment in the following minute. As previously described, three glucose data points are transmitted each minute (one current and two redundant/historical), so collisions or other interference must occur for 3 consecutive data transmissions for data to be lost. In one aspect, when a transmission is missed, the receiver 104 may be configured to successively widen its listening window until normal transmissions from the respective transmitter 102 resume. Under this approach, the transmitter listens for up to 70 seconds when first synchronizing with a transmitter 102 so it is assured of receiving a transmission from transmitter 102 under normal conditions.

In the manner described above, in accordance with the embodiments of the present invention, there is provided a continuous glucose monitoring and management system in accordance with one embodiment of the present invention includes a sensor configured to detect one or more glucose levels, a transmitter

operatively coupled to the sensor, the transmitter configured to receive the detected one or more glucose levels, the transmitter further configured to transmit signals corresponding to the detected one or more glucose levels, a receiver operatively coupled to the transmitter configured to receive transmitted signals corresponding to the detected one or more glucose levels, where the transmitter is configured to transmit a current data point and at least one previous data point, the current data point and the at least one previous data point corresponding to the detected one or more glucose levels.

The receiver may be operatively coupled to the transmitter via an RF communication link, and further, configured to decode the encoded signals received from the transmitter.

In one embodiment, the transmitter may be configured to periodically transmit a detected and processed glucose level from the sensor to the receiver via the RF data communication link. In one embodiment, the transmitter may be configured to sample four times every second to obtain 240 data points for each minute, and to transmit at a rate of one data point (e.g., an average value of the 240 sampled data points for the minute) per minute to the receiver.

The transmitter may be alternately configured to transmit three data points per minute to the receiver, the first data point representing the current sampled data, and the remaining two transmitted data points representing the immediately past two data points previously sent to the receiver. In this manner, in the case where the receiver does not successfully receive the sampled data from the transmitter, at the subsequent data transmission, the immediately prior transmitted data is received by the receiver. Thus, even with a faulty connection between the transmitter and the receiver, or a failed RF data link, the present approach ensures that missed data points may be ascertained from the subsequent data point transmissions without retransmission of the missed data points to the receiver.

The transmitter may be configured to encode the detected one or more glucose levels received from the sensor to generate encoded signals, and to transmit the encoded signals to the receiver. In one embodiment, the transmitter may be configured to transmit the encoded signals to the receiver at a transmission rate of one



data point per minute. Further, the transmitter may be configured to transmit the current data point and the at least one previous data points in a single transmission per minute to the receiver. In one aspect, the current data point may correspond to a current glucose level, and where the at least one previous data point may include at least two previous data points corresponding respectively to at least two consecutive glucose levels, the one of the at least two consecutive glucose levels immediately preceding the current glucose level.

In a further embodiment, the receiver may include an output unit for outputting the received transmitted signals corresponding to one or more glucose levels. The output unit may include a display unit for displaying data corresponding to the one or more glucose levels, where the display unit may include one of a LCD display, a cathode ray tube display, and a plasma display.

The displayed data may include one or more of an alphanumeric representation corresponding to the one or more glucose levels, a graphical representation of the one or more glucose levels, and a three-dimensional representation of the one or more glucose levels. Moreover, the display unit may be configured to display the data corresponding to the one or more glucose levels substantially in real time.

Further, the output unit may include a speaker for outputting an audio signal corresponding to the one or more glucose levels.

In yet a further embodiment, the receiver may be configured to store an identification information corresponding to the transmitter.

The receiver may be further configured to perform a time hopping procedure for synchronizing with the transmitter. Alternatively, the receiver may be configured to synchronize with the transmitter based on the signal strength detected from the transmitter, where the detected signal strength exceeds a preset threshold level.

The transmitter in one embodiment may be encased in a substantially water-tight housing to ensure continuous operation even in the situation where the transmitter is in contact with water.

Furthermore, the transmitter may be configured with a disable switch which allows the user to temporarily disable the transmission of data to the receiver when

the user is required to disable electronic devices, for example, when aboard an airplane. In another embodiment, the transmitter may be configured to operate in an additional third state (such as under Class B radiated emissions standard) in addition to the operational state and the disable state discussed above, so as to allow limited operation while aboard an airplane yet still complying with the Federal Aviation Administration (FAA) regulations. Additionally, the disable switch may also be configured to switch the transmitter between various operating modes such as fully functional transmission mode, post-manufacture sleep mode, and so on. In this manner, the power supply for the transmitter is optimized for prolonged usage by effectively managing the power usage.

Furthermore, the transmitter may be configured to transmit the data to the receiver in predetermined data packets, encoded, in one embodiment, using Reed Solomon encoding, and transmitted via the RF communication link. Additionally, in a further aspect of the present invention, the RF communication link between the transmitter and the receiver of the continuous glucose monitoring system may be implemented using a low cost, off the shelf remote keyless entry (RKE) chip set.

The receiver in an additional embodiment may be configured to perform, among others, data decoding, error detection and correction (using, for example, forward error correction) on the encoded data packets received from the transmitter to minimize transmission errors such as transmitter stabilization errors and preamble bit errors resulting from noise. The receiver is further configured to perform a synchronized time hopping procedure with the transmitter to identify and synchronize with the corresponding transmitter for data transmission.

Additionally, the receiver may include a graphical user interface (GUI) for displaying the data received from the transmitter for the user. The GUI may include a liquid crystal display (LCD) with backlighting feature to enable visual display in dark surroundings. The receiver may also include an output unit for generating and outputting audible signal alerts for the user, or placing the receiver in a vibration mode for alerting the user by vibrating the receiver.

More specifically, in a further aspect, the receiver may be configured to, among others, display the received glucose levels on a display section of the receiver

either real time or in response to user request, and provide visual (and/or auditory) notification to the user of the detected glucose levels being monitored. To this end, the receiver is configured to identify the corresponding transmitter from which it is to receive data via the RF data link, by initially storing the identification information of the transmitter, and performing a time hopping procedure to isolate the data transmission from the transmitter corresponding to the identification information and thus to synchronize with the transmitter. Alternatively, the receiver may be configured to identify the corresponding transmitter based on the signal strength detected from the transmitter, determined to exceed a preset threshold level.

A method in accordance with one embodiment of the present invention includes the steps of receiving an identification information corresponding to a transmitter, detecting data within a predetermined RF transmission range, determining whether the detected data is transmitted from the transmitter, decoding the detected data, and generating an output signal corresponding to the decoded data.

In one embodiment, the step of determining whether the detected data transmission is transmitted from the transmitter may be based on the received identification information. In another embodiment, the step of determining whether the detected data transmission is transmitted from the transmitter may be based on the signal strength and duration of the detected data within the predetermined RF transmission range.

In a further embodiment, the step of decoding may also include the step of performing error correction on the decoded data. Moreover, the step of decoding may include the step of performing Reed-Solomon decoding on the detected data.

Additionally, in yet a further embodiment of the present invention, transmitter identification information may not be included in the transmitted data from the transmitter to the receiver. Rather, the receiver may be configured to determine the transmitter identification information from the received data by using Reed Solomon decoding. More specifically, when decoding the first data packet received from a transmitter, the receiver may be configured to set the value corresponding to the transmitter identification information to zero, and to indicate to the Reed Solomon decoder that the transmitter identification information is known to be incorrect. The

Reed Solomon decoder may then be configured to use this information to more effectively “correct” during the error correction procedure, and therefore to recover the transmitter identification information from the received data. Indeed, in subsequent data packets, the received pads and the received data packet with the known transmitter identification information are used to facilitate with the error detection.

In the manner described, the present invention provides a continuous glucose monitoring system that is simple to use and substantially compact so as to minimize any interference with the user's daily activities. Furthermore, the continuous glucose monitoring system may be configured to be substantially water-resistant so that the user may freely bathe, swim, or enjoy other water related activities while using the monitoring system. Moreover, the components comprising the monitoring system including the transmitter and the receiver are configured to operate in various modes to enable power savings, and thus enhancing post-manufacture shelf life.

Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A data monitoring and management system, comprising:  
a communication link;  
a transmitter operatively coupled to the communication link, the transmitter  
5 configured to transmit a data packet; and  
a receiver operatively coupled to the communication link, the receiver  
configured to receive transmitted data packet, the receiver further configured to  
receive one or more further data packets from the transmitter when the transmitter  
identification is verified.  
10
2. The system of claim 1 wherein the communication link includes an RF  
communication link.
3. The system of claim 1 wherein the transmitter is configured to transmit the  
15 data packet at each predetermined time interval.
4. The system of claim 3 wherein the predetermined time interval is one minute.
5. The system of claim 1 wherein the receiver is further configured to perform  
20 error correction on the received data packet.
6. The system of claim 1 wherein the receiver is configured to verify the  
transmitter identification based on the transmitter identification information encoded  
with the data packet.  
25
7. The system of claim 1 further including a sensor configured to detect one or  
more glucose levels, wherein the sensor is configured to be in signal communication  
with the transmitter.
8. The system of claim 7 wherein the sensor is disposed substantially in physical  
30 contact with the transmitter.

9. The system of claim 7 wherein the transmitter is configured to convert a sensor signal received from the sensor into a corresponding data for transmission to the receiver.

5

10. The system of claim 7 further including a medication delivery unit operatively coupled to the receiver, the medication delivery unit configured to determine a medication administration protocol based on the signals received from the receiver.

10

11. The system of claim 10 wherein the medication delivery unit includes an insulin pump, and further wherein the medication administration protocol includes one or more of a bolus calculation, and a basal profile modification.

15

12. The system of claim 10 wherein the receiver is configured to determine a glucose level corresponding to the sensor signal, and further, wherein the receiver is configured to output the glucose level information.

20

13. The system of claim 10 wherein the medication delivery unit is configured to wirelessly communicate with the receiver.

25

14. A continuous glucose monitoring and management system, comprising:  
an RF communication link;  
a transmitter operatively coupled to the communication link, the transmitter configured to periodically transmit a data packet at each predetermined time interval;  
and

30

a receiver operatively coupled to the communication link, the receiver configured to receive a first transmitted data packet, the receiver further configured to receive one or more subsequent data packets from the transmitter when the transmitter identification is verified;

wherein the receiver is configured to verify the transmitter identification based on the transmitter identification information encoded with the first transmitted data packet.

5        15.     The system of claim 14 wherein the data packets received from the transmitter correspond to a respective measured glucose level of a patient.

10       16.     The system of claim 15 further including an insulin pump operatively coupled to the receiver, the insulin pump configured to determine an insulin administration protocol based on the signals received from the receiver.

17.     The system of claim 16 wherein the insulin administration protocol includes one or more of a bolus determination, and a basal rate modification determination.

15       18.     The system of claim 16 wherein the insulin pump is disposable.

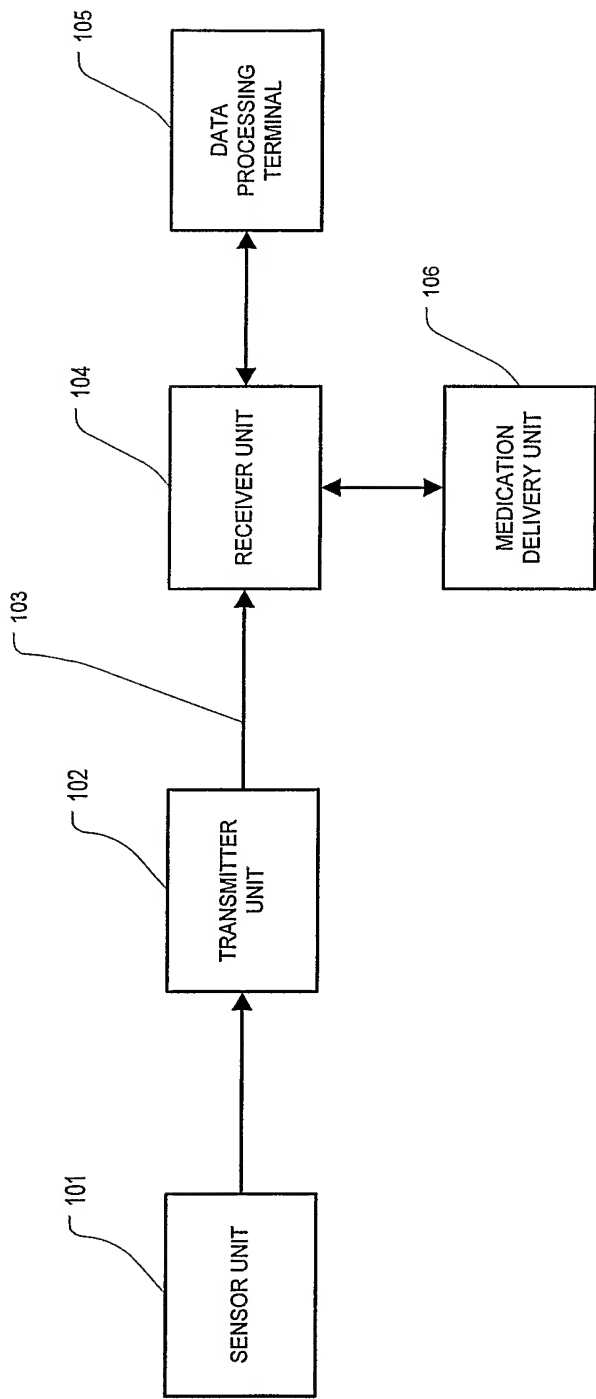
19.     The system of claim 14 wherein the predetermined time interval for transmitter data packet transmission includes one transmission per minute.

20       20.     A method of providing continuous glucose monitoring and management system, comprising the steps of:

         providing an RF communication link;

         periodically transmitting a data packet at each predetermined time interval over the RF communication link;

25           receiving a first transmitted data packet over the RF communication link; and  
         receiving one or more subsequent data packets over the RF communication link when the transmission identification is verified from the first transmitted data packet.



100

FIGURE 1



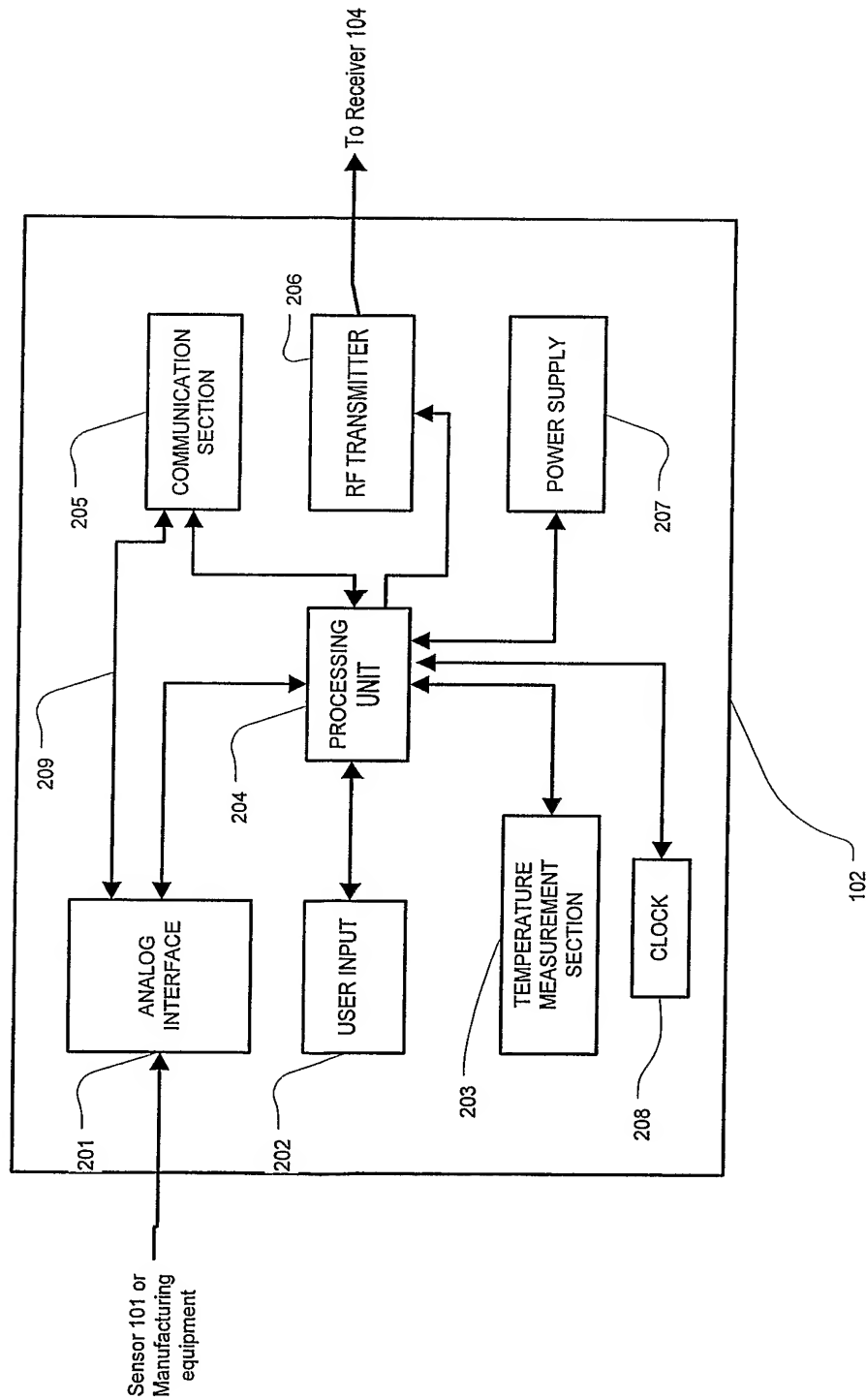


FIGURE 2

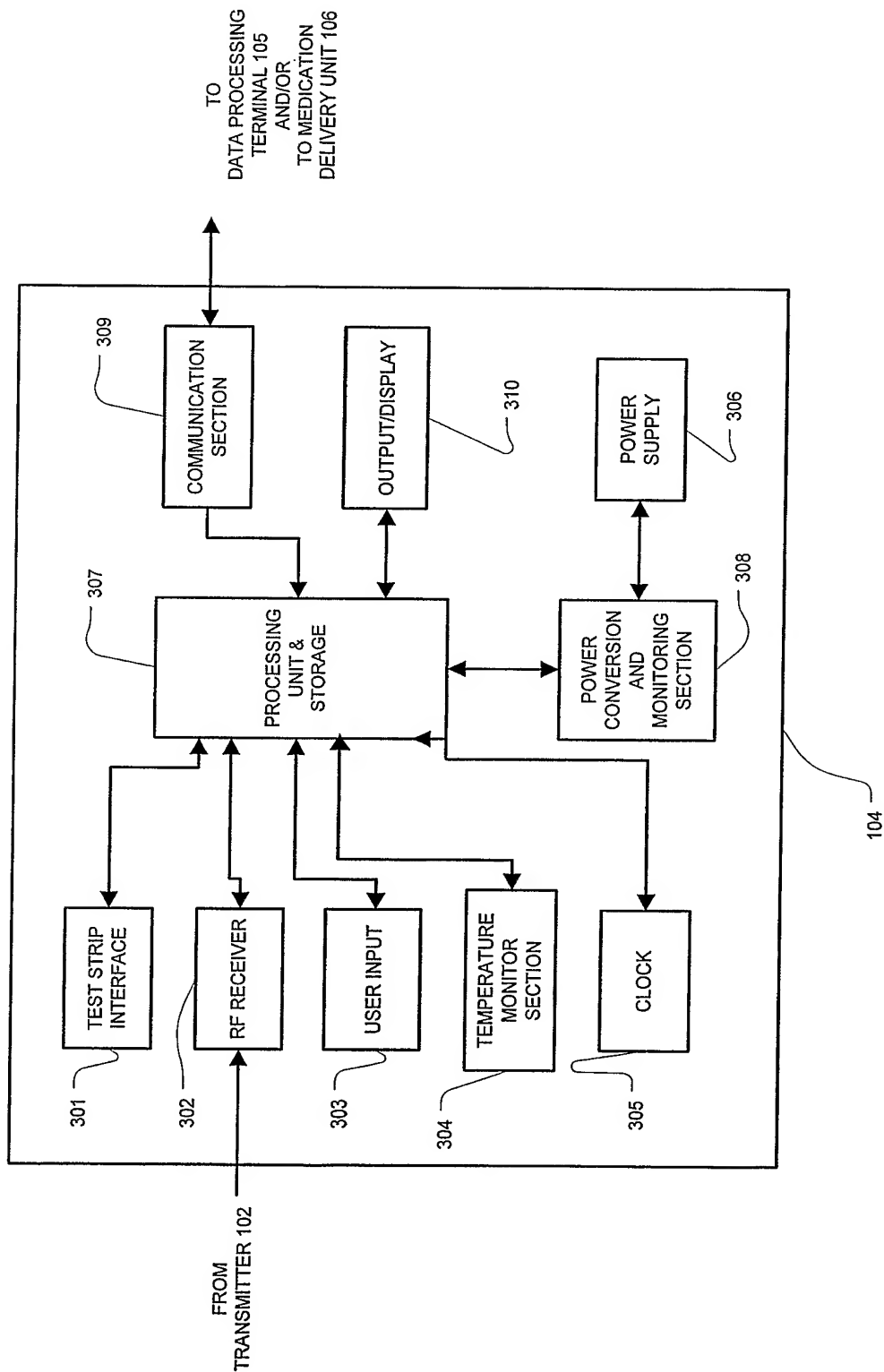


FIGURE 3

Byte	Contents
0	TxTime
1 to 14	Application payload

FIGURE 4

Received Packet Contents		
0	Dotting pattern	Number of bits captured varies
1	Start indicator	13 bits
1	Packed data	15 symbols
2	Parity Symbols	6 symbols
	Total	21 symbols

FIGURE 8

<b>Reed Solomon Block contents</b>		
<b>1</b>	<b>Packed data</b>	<b>15 bytes</b>
<b>2</b>	<b>TX ID, LSB</b>	<b>1 byte</b>
<b>3</b>	<b>TX ID, least middle SB</b>	<b>1 byte</b>
<b>4</b>	<b>TX ID, most middle SB</b>	<b>1 byte</b>
<b>5</b>	<b>TX ID, MSB</b>	<b>1 byte</b>
	<b>Zero pad</b>	<b>230 bytes</b>
	<b>Parity Symbols</b>	<b>6 bytes</b>
	<b>Total</b>	<b>255 bytes</b>

FIGURE 5A

<b>Depadded Block contents</b>		
<b>1</b>	<b>Packed data</b>	<b>15 bytes</b>
<b>2</b>	<b>Parity Symbols</b>	<b>6 bytes</b>
	<b>Total</b>	<b>21 bytes</b>

FIGURE 5B

<b>Transmit Packet contents</b>		
<b>0</b>	<b>0x00 0x00 0x15 0x67</b>	<b>4 bytes</b>
<b>1</b>	<b>Depadded Block contents</b>	<b>21 bytes</b>

FIGURE 5C

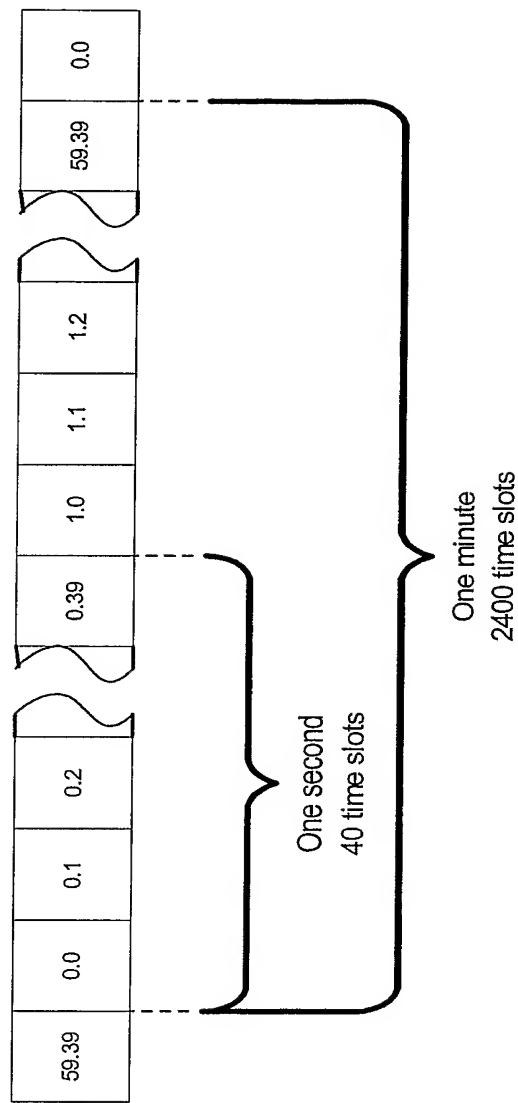


FIGURE 6

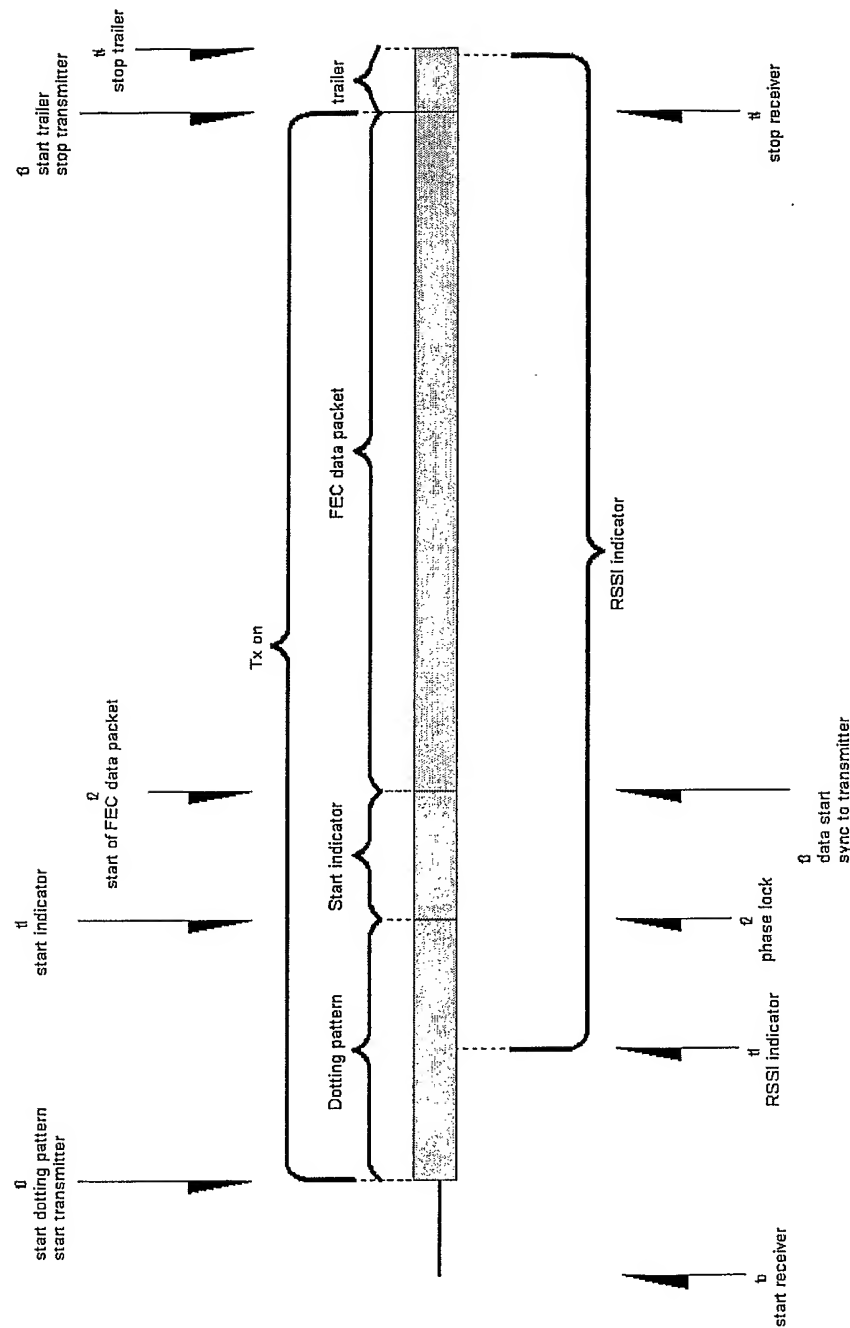


FIGURE 7

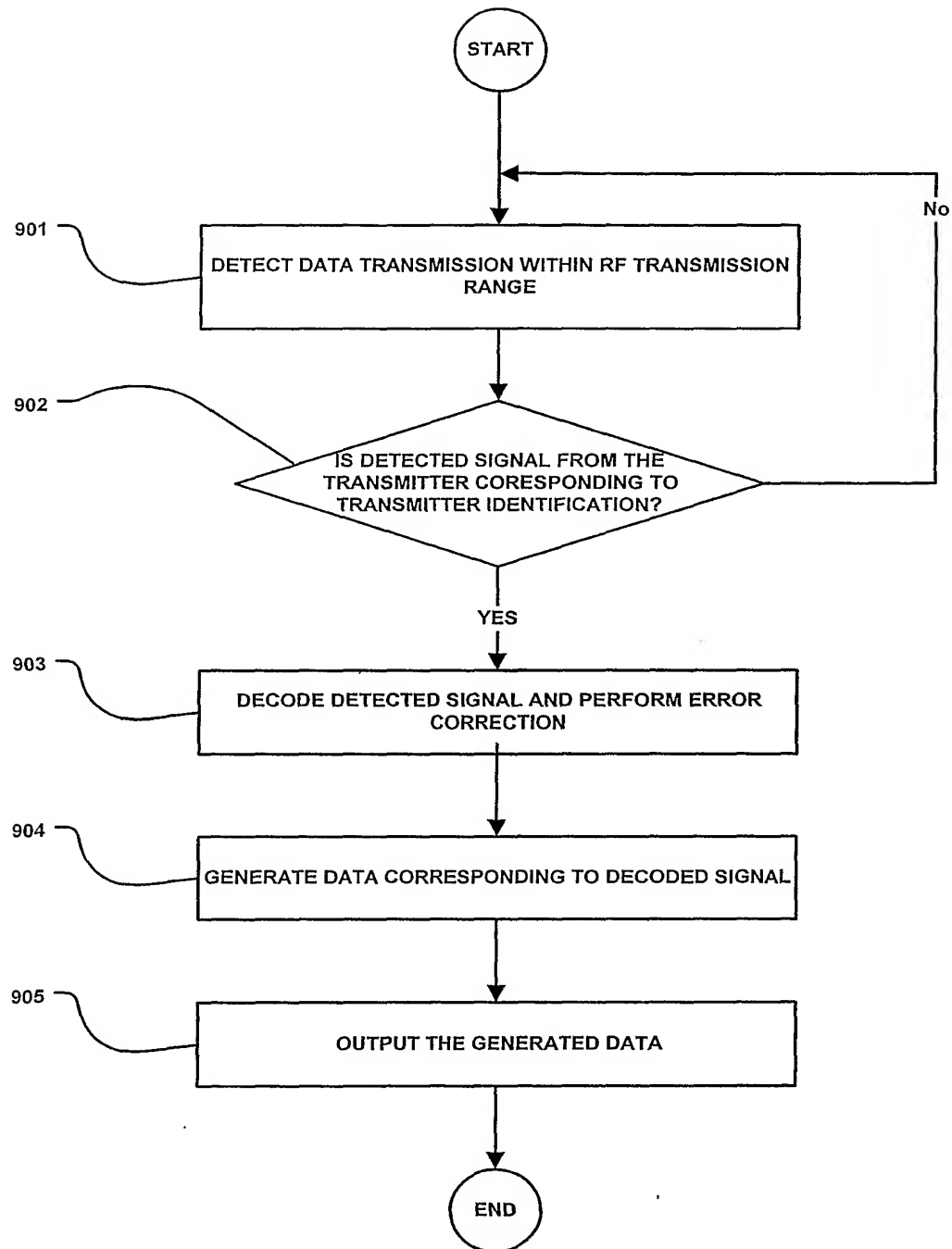


FIGURE 9